

REMARKS/ARGUMENTS

Claims 1-78 are pending. Reconsideration is respectfully requested.

1. Rejection of Claims 71-78 Under § 112

Claims 71-78 stand rejected under 35 U.S.C. 112, second paragraph as being indefinite, because claim 71 recites both:

(d) transmitting the light pulses generated by the light source along a light path including an aperture through which eye-safe light pulses are propagated **having an output fluence not less than 4 J/cm²**;

(e) optically diffusing the light pulses along the light path so that an integrated radiance of the output light pulses is reduced to an **eye-safe value**;

The Examiner states that eye safe values are defined on page 9 in the discussion of MPE, and that using maximum values for the MPE equation, the maximum eye safe value is less than the 4 J/cm² recited in claim 71.

The Applicants respectfully traverse this rejection, because the Examiner is not properly applying the meaning of “eye-safe value” as defined in the disclosure. Specifically, there is no indefiniteness, because the 4.0 J/cm² figure refers to the *output fluence* of the device (p. 68, line 19); while the 0.6 J/cm² figure calculated by the Examiner as a reference for the statement of eye safety is the *Maximum Permissible Exposure* (MPE), which refers to the fluence that is considered safe for the eye, when measured at the cornea according to published international standards. Thus it is quite possible, and in fact has been demonstrated experimentally, that the device described in this patent application produces an **output fluence** of greater than 4 J/cm², while simultaneously producing a **fluence at the cornea** well below the MPE.

This important distinction is further clarified by reference to the definitions stated in the patent application. *Output fluence* is defined on p.40, lines 14-16:

“Throughout this patent application the term output fluence is intended to describe the fluence at the output aperture or output window of the dermatologic treatment apparatus. For purposes of clarification, the output fluence of the device is also termed below as F_{source}.”

Maximum permissible exposure is defined on p. 47, line 20 through p. 48, line 4:

“To evaluate eye safety under the ANSI, IEC or ICNIRP guidelines, two values are calculated and compared. The first is the Maximum Permissible Exposure (MPE). This value is the fluence or irradiance that is considered safe for the human eye, measured at the cornea. The actual value of the MPE varies greatly depending on the characteristics of the light source in question...

The second value, “ F_{cornea} ”, is the fluence produced at the cornea from a particular light source, as measured through a pair of apertures limiting the angle of acceptance to 100 milliradians... The value of F_{cornea} depends on both the fluence produced by the device at its output (the “output fluence”), as well as how the light diverges from the output as it propagates toward the eye. **For any light source, if F_{cornea} is less than the MPE for all possible distances between the source and the eye, the device is considered eye-safe.**” (emphasis added)

Thus the output fluence of a light source (F_{source}); the fluence this light source would produce at the cornea F_{cornea} (measured as defined in the international standards), and the MPE associated with this light source, are all quite different parameters. More specifically, it is possible to have an output fluence (F_{source}) that is greater than 4 J/cm^2 while having a cornea fluence F_{cornea} that is less than the MPE for all possible distances between the source and the eye (thus making the device eye-safe as recited in claim 71). Therefore, the objection cited, i.e., that the output fluence value stated is greater than the MPE value calculated, cannot be the basis for a determination that Claims 71-78 are indefinite.

For these reasons, it is respectfully submitted that the Examiner was mis-applying MPE in the rejection of claims 71-78, and thus this rejection should be withdrawn.

2. Rejection of Claims 1-2, 5, 8, 16-18, 20-34 and 36-44 Under §103(a)

Claims 1-2, 5, 8, 16-18, 20-34 and 36-44 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,743,901 (Grove I) in view of U.S. Patent 6,106,514 (O'Donnell). The Applicants respectfully traverse this rejection.

To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974); MPEP 2143.03. It is respectfully submitted that Grove I and O'Donnell fail to teach or

suggest all the limitations of the rejected claims. For example, independent claims 1 and 31 recite, among other things, the combination of an optical diffuser disposed along the light path so that an integrated radiance of the output light pulses is reduced to an eye-safe value, and the output fluence of a light pulse emitted by the apparatus is not less than 4 J/cm². Eye safe value is explained above and defined in the specification as $F_{\text{cornea}} < \text{MPE}$ (see page 48, lines 2-4). The Examiner has failed to establish that the Grove I device is eye safe, or even attempted to compare F_{cornea} to MPE of the Grove I device to determine if it produces an eye safe output with a fluence of at least 4 J/cm².

In fact, Grove I actually teaches away from the eye-safe output as claimed, as the objectives of this reference are to provide a diode mount designed to permit high power and long pulse operation, a microlens array to improve array brightness, and an optical condenser to reduce the target area (see Col. 3, lines 23-35), all in order to increase power, concentration, fluence and brightness (see Col. 3, lines 4-20). All of these objectives and solutions decrease the eye safety of the output, not ensure eye safety as claimed.

There is sufficient information in Grove I to determine that the device therein is not eye safe as recited in rejected claims 1 and 31. Specifically, Grove I describes a high fluence diode laser device and method for the fabrication thereof with the following typical parameters: wavelength of 750 – 950 nm (column 4, line 15); output area of 0.8 cm² (column 6, line 39); fluence of 10 – 100 J/cm² (column 7, line 27); and a pulse duration of up to 30 ms (column 7, line 24). In general, the hazard from light-based devices like those described decreases with increasing pulse duration and increasing aperture area (as well as with lower output fluence). Thus the least hazardous device envisioned by Grove I would be a device of approximately 800 nm wavelength (the hazard varies only slightly over the 750 nm – 950 nm range), 30 ms pulse duration, 0.8 cm² output area, and fluence of 10 J/cm². Such a device with an output fluence of 10 J/cm² and an output area of 0.8 cm² has an output energy of 8 J. Although the divergence of laser light from each laser diode bar is approximately 10 degrees by 40 degrees (full-width half-maximum, or FWHM), the combination of the cylindrical microlenses and the non-imaging

condenser results in a divergence from the output aperture of approximately 20 degrees by 20 degrees FWHM, or approximately 0.35 radians. For calculation of the fluence on the cornea of the eye (F_{cornea}) produced by a laser device, a minimum distance between the output aperture of the device and the eye is used, based on published standards, as this is typically the most unsafe region. (See, for example, IEC 60825-1, Safety of laser products, p. 35.) For this source the appropriate distance is 10 cm. Further, for a laser source of output energy E at distance d and divergence angle ϕ , the fluence on the cornea is calculated as follows (see page 49, line 24 of the specification):

$$F_{\text{cornea}} = (4 E) / (\pi [d \phi]^2) = (4 \times 8) / (3.14 \times [10 \times 0.35]^2)$$

Thus, $F_{\text{cornea}} = 0.83 \text{ J/cm}^2$ for the Grove I device.

The Maximum Permissible Exposure (MPE) is given by:

$$\text{MPE} = 18 t^{0.75} C_4 C_6 \text{ (J/m}^2\text{)}$$

as defined on page 48, lines 9-25. For a source wavelength of 800 nm, $C_4 = 1.56$ (see page 48, line 15 of the specification); and for an "extended source" of the type here $C_6 = 66.7$ (see page 48, lines 24-25 of the specification). The parameter t is the pulse duration in seconds. Using the 30 ms value, the following MPE is obtained:

$$\begin{aligned} \text{MPE} &= 18 (30\text{ms})^{0.75} (1.56) (66.7) \text{ (J/m}^2\text{)} \\ &= 135 \text{ J/m}^2, \text{ or } = 0.0135 \text{ J/cm}^2 \text{ for the Grove I device.} \end{aligned}$$

Thus the Grove I device produces a fluence on the cornea (F_{cornea}) that is more than **sixty times above the MPE** (that is, $0.83 / 0.0135 = 61$), clearly not meeting, teaching or suggesting a device with an optical diffuser disposed along the light path so that an integrated radiance of the output light pulses is reduced to an eye-safe value, while the output fluence of the emitted light pulses is not less than 4 J/cm^2 , as recited in claims 1 and 31. Thus, it is respectfully submitted that claims 1 and 31 are not anticipated or rendered obvious by Grove I.

The Examiner states it would have been obvious to add the diffuser lens of O'Donnell to the Grove I device to reduce the risk of concentrating the light too superficially, and result in the claimed invention. The Applicants respectfully traverse this conclusion for several reasons.

First, the Examiner has failed to establish that the O'Donnell lens in the Grove I device would render the output eye safe as recited in independent claims 1 and 31. Second, the Applicants respectfully traverse the finding that one skilled in the art would have been motivated to combine Grove I and O'Donnell as suggested by the Examiner. The stated purpose in Grove I is to increase power, concentration, fluence, and brightness (see Col. 3, lines 4-20), which is achieved by the improved diode mount design, microlens array, and optical condenser (see Col. 3, lines 23-35). Diffusing the output of Grove I with the lens of O'Donnell would defeat these objectives by reducing concentration. A primary reference may not be modified in light of or combined with one or more secondary references where the result would be to render the primary reference **inoperable** for its intended purpose. In re Gordon, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). Lastly, the Applicants respectfully submit it is improper to combine Grove I and O'Donnell in support of this rejection because Grove I teaches away from such a combination. Specifically, the teachings of Grove I are concerned only with increasing power, concentration, fluence, and brightness. Yet, adding the diffuser lens of O'Donnell to the Grove I device would decrease concentration, fluence and brightness, in direct contradiction to those teachings. It is improper to combine references where the references teach away from their combination. In re Grasselli, 713 F.2d 731, 218 USPQ 769, 779 (Fed. Cir. 1983); MPEP 2145.

For these reasons, it is respectfully submitted that claim 1 and 31, and claims 2, 5, 8, 16-18, 20-30, 32-34 and 36-44 dependent thereon, are not rendered obvious by Grove I and O'Donnell.

3. Rejection of Claims 45-70 Under §103(a)

Claims 45-70 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Grove I in combination with O'Donnell and U.S. Patent 5,707,403 (Grove II). The Applicants respectfully traverse this rejection.

Just as with claims 1 and 31, independent claims 45, 54, 63 and 67 recite, among other things, the combination of an optical diffuser disposed along the light path so that an integrated

radiance of the output light pulses is reduced to an eye-safe value, and the output fluence is not less than 4 J/cm². As stated above in Part 2, Grove I does not teach or suggest such an eye safe device, the addition of O'Donnell does not appear to remedy the deficiencies of Grove I, and there is a lack of motivation (and a teaching away) from modifying Grove I with the diffuser lens of O'Donnell. Further, it is respectfully submitted that the addition of Grove II does not appear to remedy the deficiencies of Grove I and O'Donnell.

For these reasons, it is respectfully submitted claims 45, 54, 63 and 67 (and claims 46-53, 55-62, 64-66 and 68-70 dependent thereon) are not rendered obvious over Grove I, O'Donnell and Grove II.

4. Rejection of Claims 3-4 and 11-15 Under §103(a)

Claims 3-4 and 11-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Grove I in combination with O'Donnell and U.S. Patent 5,966,210 (Rosow). The Applicants respectfully traverse this rejection.

Claims 3-4 and 11-15 depend from claim 1. For the reasons set forth above in Part 2 with regard to the allowability of claim 1 over Grove I and O'Donnell, it is respectfully submitted that dependent claims 3-4 and 11-15 are allowable as well. The addition of Rosow does not appear to remedy the deficiencies of Grove I and O'Donnell.

5. Rejection of Claims 6-7, 9-10, 19 and 35 Under §103(a)

Claims 6-7, 9-10, 19 and 35 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Grove I in combination with O'Donnell and U.S. Patent 6,663,659 (McDaniel). The Applicants respectfully traverse this rejection.


Claims 6-7, 9-10, 19 and 35 depend from claims 1 or 31. For the reasons set forth above in Part 2 with regard to the allowability of claims 1 and 31 over Grove I and O'Donnell, it is respectfully submitted that dependent claims 6-7, 9-10, 19 and 35 are allowable as well. The addition of McDaniel does not appear to remedy the deficiencies of Grove I and O'Donnell.

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For the foregoing reasons, it is respectfully submitted that the claims are in an allowable form, and action to that end is respectfully requested.

Respectfully submitted,

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